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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/603,889 | 06/25/2003 | Syed F.A. Hossainy | 50623.257 | 4898 |

7590 11/30/2004

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| EXAMINER | |
|---|---|
| CHEN, BRET P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1762 | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/603,889 | HOSSAINY ET AL. |
| | Examiner | Art Unit |
| | B. Chen | 1762 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 7,21 and 25 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,8-20,22-24 and 26-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-34 are pending in this application.

### *Election/Restrictions*

Applicant's election without traverse of claims 1-6, 8-20, 22-24, 26-34 are in the reply filed on 9/9/04 is acknowledged. Claims 7, 21, 25 are withdrawn from consideration as being directed to a nonelected invention.

### *Specification*

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, **"The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.**

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) **if a process, the steps**.

Extensive mechanical and design details of apparatus should not be given.

The abstract language should be amended appropriately. It is also noted that the claimed invention is directed to a method. The examiner suggests amending the abstract to reflect same.

### *Claim Objections*

Claims 1-6, 8-20, 22-24, 26-34 are objected to because of the following informalities. Appropriate correction is required.

In claim 4, the terms "the surface" and "the stent" lacks antecedent basis.

In claim 14, the term "the stent" lacks antecedent basis.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-20, 22-24, 26-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the applicant applies a fluid and then evaporates it. It is not clear why the fluid was even applied at all. Clarification and appropriate amendments are requested.

In claim 10, the terms "functional analog" or "structural derivative" are deemed vague and indefinite.

In claim 27, the phrase "the polymer exhibits two or more glass transition temperatures" is vague and confusing. It is not clear how a material can exhibit two transition temperatures.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-6, 8-20, 22-24, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (6,099,562).** Ding discloses a method of coating an implantable device with an undercoat of polymeric material containing a biologically active material followed by a top coat (col.3 lines 41-47). The implantable device can be a stent (col.3 line 5) and the undercoat can contain a polymer, an active agent, and a solvent (col.4 lines 8-21). In one embodiment, the solvent can be evaporated rendering the undercoat useful for controlled drug release without further curing (col.5 lines 18-22). The topcoat is free from pores, porosigens, or materials capable of eluting. However, the reference remains silent on 2% residual fluid content.

It is noted that the reference clearly teaches that the solvent is evaporated without further curing. It is the examiner's position that one skilled in the art reading Ding would realize that the coating is sufficiently dry for use as a stent. It would have been obvious to the skilled artisan to recite a specific residual fluid amount with the expectation of obtaining similar results in the absence of a showing of unexpected results.

The limitations of 2-6, 8-20, 22-24, 26-34 have been addressed above.

**Claims 1-6, 8-20, 22-24, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (6,358,556).** Ding discloses a method of coating a stent capable of long-term delivery of biologically active materials (col.2 lines 62-67) wherein the coating can be solution of polymeric material with a biologically active species in a solvent (col.3 lines 29-45). The solvent can be evaporated (col.3 lines 59-64). However, the reference remains silent on 2% residual fluid content.

This issue has been addressed above and is applied here for the same reasons.

In addition, the reference remains silent on applying a fluid and evaporating the fluid. One skilled in the art would expect that applying a fluid and removing it again is functionally equivalent to not applying a fluid at all. Hence, it would have been obvious to the skilled artisan to apply a fluid and evaporate it with the expectation of obtaining equivalent results.

The limitations of 2-6, 8-20, 22-24, 26-34 have been addressed above.

Hansen (6,669,980) has been cited as relevant art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Chen whose telephone number is (571) 272-1417. The examiner can normally be reached on 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bc
11/28/04

BRET CHEN
PRIMARY EXAMINER